



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

DEC 14 1999

MEMORANDUM BARCODE D260752

SUBJECT: Emergency Exemption Request for Thiamethoxam (Chemical # , DP Barcode ) Use as a Canola Seed Treatment in North Dakota

FROM: Kevin Costello, Geologist  
Amer al-Mudallal, Chemist  
and  
Brian Montague, Biologist  
Environmental Risk Branch 1  
Environmental Fate and Effects Division (7507C)

*Kevin Costello*  
*Amer al-Mudallal*  
*Brian Montague*

12/14/99

12/14/99

12/14/99

THRU: Arnet Jones, Branch Chief  
Environmental Risk Branch 1  
Environmental Fate and Effects Division (7507C)

*Arnet Jones*

12/14/99

TO: Mary Waller/Tom Ellwanger, PM 21 and Steve Schaible  
Registration Division (7505C)

The State of North Dakota has submitted a Section 18 emergency exemption request for the use of thiamethoxam (as a component of Helix) as a canola seed treatment. Since GENEEC and SCI-GROW are not designed to estimate runoff or leaching for seed treatment pesticides, there are uncertainties in the predictive potential of the Tier 1 modeling for drinking water assessment. The noted uncertainties in the water assessment, however, are not expected to substantially decrease the conservativeness of the Tier 1 modeling results.

GENEEC modeling simulated thiamethoxam concentrations in drinking water of 0.55 ppb for a 2-inch incorporation at the maximum annual application rate (acute) and 0.2 ppb for the 56 day average concentration (chronic). If the incorporation is only to one inch, the corresponding values are 1.1 and 0.41 ppb, respectively. SCI-GROW modeling simulated thiamethoxam concentrations in ground water used as drinking water of 0.6 ppb.

### Uncertainties in the Modeling

The main uncertainty in the Tier 1 FQPA water assessment is the use of GENEEC and SCI-GROW models to estimate runoff and leaching of thiamethoxam from seed treatment use. These models do not account for the pesticide sorption to the seed coat. For purposes of this assessment, it is assumed that these pesticides desorb from the seed coat and that all of the pesticide is available for transport or sorption to the soil. This assumption is expected to provide a conservative leaching and runoff scenario.



## Environmental Fate

The model input parameters for thiamethoxam shown below indicate that this insecticide is both mobile and persistent in soil. The aqueous degradation rates of thiamethoxam are significantly lower than the aerobic soil metabolism half-life, indicating that thiamethoxam might not persist long in surface water bodies.

The drinking-water screening values described above apply only to this current Section 18 request. If the request is granted, then the proposed application rate of 0.022 lb ai/acre will be the highest thiamethoxam application rate, as it will be the only current use of thiamethoxam in the United States. When the Agency considers the Section 3 registration request for canola and many other crops in the spring of 2000, the maximum application rates from all the proposed uses will be considered.

### GENEEC AND SCI-GROW INPUT PARAMETERS FOR THIAMETHOXAM

Input Parameters for GENEEC			
Input Variable	Input Value	Comments	Source
Chemical Name	Thiamethoxam		Label
Solubility	4100 mg/l		Chemistry data submitted by the registrant
Hydrolysis Half-life (pH 7)	643 days	Maximum Value	MRID # 44703417
Aerobic Soil Metabolism Half-life	409 days	90 <sup>th</sup> Upper Percentile of 365, 408, 385 days	MRID # 44703418, 44703419, 44703501
Aqueous Photolysis Half-life	3.1 days	Maximum Value at pH 5	MRID # 44715025
Aerobic Aquatic Metabolism Half-life	16.2 days	Maximum Value	MRID # 44715032
K <sub>oc</sub>	33.1 ml/g	Minimum Value	MRID # 44703502
Application Rate	0.022 lb. a.i./acre		Label
Number of Applications Per Season	1		Label

### Input Parameters for SCI-GROW

Input Variable	Input Value	Comments	Source
Chemical Name	Thiamethoxam		Label
Aerobic Soil Metabolism Half-life	386 days	Average Value	MRID # 44703418, 44703419, 44703501
K <sub>oc</sub>	40.7 ml/g	Median Value for US Soils	MRID # 44703502
Application Rate	0.022 lb. a.i./acre		Label
Number of Applications Per Season	1		Label

### **Ecological Risk**

Based on the partially reviewed ecological effects data submitted by the registrant, the canola seed-treatment use of thiamethoxam seems unlikely to pose a risk to non-target organisms. No effects were seen in fish nor aquatic plants listed below at the highest concentration of thiamethoxam tested. Effects were seen in aquatic invertebrates at concentrations significantly greater than those simulated by GENEEC (lowest effect level was 35 ppb for midge larvae).

Thiamethoxam is very highly toxic to honeybees, but the likelihood of honeybee exposure to incorporated, treated seed is small. The toxicity to bees will be a greater concern when proposed foliar applications of thiamethoxam are considered in spring, 2000.

The Canadian Pest Management Regulatory Agency (PMRA) has reviewed avian toxicity studies submitted by Novartis. EFED will perform a secondary review of these documents for the full registration in spring, 2000. Results of the Canadian reviews are listed in the table below. Based on the proposed application rate of thiamethoxam on canola, and the magnitude of the toxicity values below, thiamethoxam use on canola is not expected to pose a risk to birds.

Below is a partial list of submitted studies. The most sensitive species in particular classes of non-target organisms are included in this table. The full list of submitted studies will be included in the full registration package.

Species Tested	Toxicity	Endpoints Affected	EPA Identification
Mallard duck	14 Day LD50=576 mg/Kg NOEL not determined	Mortality & Wt. Loss	Reviewed by Canada PMRA
Mallard duck	NOEC=300 ppm LOEC=900 ppm	Wt loss in parental males	Reviewed by Canada PMRA
Rainbow trout	96 hr LC50>100 ppm	none	44714916
Bluegill sunfish	96 hr LC50>114 ppm	none	44714917
Midge larvae	48 hr EC50=0.035 ppm 48 hr NOEC=0.013ppm	mortality	44714918
Sheepshead minnow	96 hr LC50>111 ppm	none	44714920
Eastern oyster	96 hr EC50>119 ppm	shell deposition	44714921
Mysid	96 hr LC50=6.9 ppm	mortality	44714922
Rainbow trout early life effects	56 D LOEC>20 ppm NOEC>20 ppm	20 ppm:No effects to growth or reproduction	44714923
<i>Daphnia</i> Lifecycle	21 D LOEC=101 ppm NOEC=50 ppm	# neonates produced	44714924
Pondweed <i>Lemna gibba</i>	14 D EC50>90 ppm	no effects noted	44714925
Alga <i>Selenastrum capricornutum</i>	5 D EC50>97 ppm	no effects noted	44714926
Honeybee	24 hr Contact LD50=0.024 ug ai/bee	mortality	447714927
	48 hr Oral LD50= 0.005 ug ai/bee	mortality	447714927

BARCODE: D260752

CASE: 292376  
SUBMISSION: S570289

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 12/16/99  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: EMERGENCY EXEMP ACTION: 510 SEC18-OC F/F USE  
RANKING : 5 POINTS ()  
CHEMICALS: 060109 Thiamethoxam (ISO proposed common name)

%

ID#: 00ND0001

COMPANY:

PRODUCT MANAGER: 05 ROBERT FORREST 703-308-9376 ROOM: CM2 248  
PM TEAM REVIEWER: STEPHEN SCHAIBLE 703-308-9362 ROOM: CM2 267  
RECEIVED DATE: 10/26/99 DUE OUT DATE: 12/15/99

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 260752 EXPEDITE: N DATE SENT: 11/02/99 DATE RET.: / /  
CHEMICAL: 060109 Thiamethoxam (ISO proposed common name)  
DP TYPE: 001

CSF: N LABEL: Y  
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 11/22/99  
DIV : EFED 11/03/99 / / NEGOT DATE: / /  
BRAN: ERB1 11/03/99 12 / 14 / 99 PROJ DATE: / /  
SECT: IO 11/03/99 / /  
REVR : KCOSTELL 11/03/99 / /  
CONTR: / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review this section 18 request to use the product Helix (containing 4 active ingredients) on canola seed to control flea beetles. Please evaluate whether exposure from the unregistered active ingredient thiamethoxam from this seed treatment will result in unacceptable exposure to non-target organisms, including Federally-listed species. Please also indicate if there are any environmental fate or groundwater concerns. If I can be of help, please call. Steve Schaible (308-9362)

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
260635	HIB/IO	10/28/99	11/17/99	Y	N	Y
260750	EAB/IO	11/02/99	11/22/99	Y	N	Y
260760	RAB2	11/02/99	11/22/99	Y	N	Y

COMMISSIONER OF AGRICULTURE  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

October 8, 1999

Ms. Meredith Laws  
Director, Emergency Response Section  
2<sup>nd</sup> Floor  
Document Processing Desk  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Dear Ms. Laws:

As the state agency designated by the Governor to coordinate and implement FIFRA, as amended, the North Dakota Department of Agriculture is hereby submitting an application for a specific exemption for the use of Helix seed treatment for use on canola to control flea beetles and certain seed borne and damping off diseases.

The department strongly supports this exemption since flea beetle pressures in North Dakota this year were extreme as evidenced by information from North Dakota State University that the Northern Canola Growers have submitted to EPA this year. The flea beetle pressure was so severe that the control period offered by Gaucho was not long enough to prevent excessive damage. This package for Helix will ease the emergency condition further, by providing control of flea beetles under severe pressure.

Thank you for your consideration of this application. If you have any questions regarding this Section 18 application, please contact me at (701) 328-4756.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Olson".

Jeff Olson, Manager  
Plant Industries

JO:jo

Enc.

## HELIX SECTION 18 APPLICATION

Section 18 of amended FIFRA provides the Administrator may exempt a state or federal agency from provisions of FIFRA if a determination is made that emergency conditions exist which require such exemption. The North Dakota Department of Agriculture is applying for a specific exemption to use Helix® as a seed treatment on canola to control flea beetles.

Information required in 40 CFR 166.20(a):

I. **Type of Exemption:** Specific

II. **Contact Person:**

Mr. Jeff Olson  
Manager, Plant Industries  
ND Department of Agriculture  
600 E Blvd-6th Flr-State Capitol  
Bismarck, ND 58505-0020

Qualified Expert:  
Dr. Janet Knodel  
NDSU  
North Central Research Extension Center  
Minot, ND 58701

III. **Description of the Pesticide**

This application for a specific exemption is for the use of Helix® seed treatment, a product containing the active ingredients thiamethoxam, difenoconazole, and fludioxinil. The product is manufactured by Novartis Crop Protection, PO Box 18300, Greensboro, NC 27419.

A copy of the additional labeling proposed for this specific exemption for use on canola is attached to this application.

IV. **Description of the Proposed Use**

- **Sites to be Treated:** Canola
- **Method of application:** Seed Treatment
- **Rate of application:** The application rate of Helix will be 23 fluid ounces of product per 100 pounds of seed. Canola is typically planted at 15 pounds per

acre. This would equal approximately 1.38 ounces of product per acre.

- Total Units to be Treated: 24,000 cwt. This is based on use of the product on 400,000 acres of canola in the U.S.
- Total Amount of Pesticide to be Used: 552,000 ounces of total product will be used based on 23 fluid ounces of product per cwt. of seed.
- Use Season: Jan. 1, 2000 – March 1, 2000
- Additional Restrictions, User Precautions and Requirements, Qualifications of Applicators, etc.: None.

Canola seed will be treated in North Dakota and possibly in Idaho under this exemption. Canola seed may be shipped to the states of Minnesota, Montana, Wisconsin, South Dakota and Washington. Each of these states will provide economic loss data to the EPA shortly.

#### **V. Alternative Methods of Control**

Presently only one product is registered for seed treatment use on canola to control flea beetles. This product is Gaucho, which is a systemic, seed-applied insecticide designed to control flea beetles and aphids. It contains the active ingredient imidacloprid.

However, as shown in the enclosed memorandum from Dr. Janet Knodel of North Dakota State University, Gaucho failed to provide control of flea beetles in 1999 under the severe pressure experienced in North Dakota. Trap counts from this fall indicate even more extreme infestations are likely to occur again next year.

#### **VI. Effectiveness of Proposed Use**

Please refer to the enclosed trial data from Dr. Janet Knodel.

#### **VII. Discussion of Residues for Food Use**

Novartis Crop Protection has submitted a petition to amend 40 CFR part 180 by establishing a tolerance for the residues of difenoconazole on the raw agricultural commodity canola seed at .01 ppm. The Notice of Filing for this petition was published in 64 Federal Register, Number 86 (May 5, 1999). The Notice of filing for the pesticide petition to amend 40 CFR part 180 by establishing a tolerance for residues of thiamethoxam in or on the raw agricultural commodity canola at .02 ppm has been submitted. These petitions are included with this application.



Residue chemistry data submitted to the U.S. EPA in support of the pending tolerance petition for residues of thiamethoxam and difenoconazole in or on canola and its processed commodities is included with this application in appendix A. This data covers plant metabolism, the analytical method and magnitude of residues.

**VIII. Discussion of Risk Information**

- A. The Toxicological Profile of difenoconazole and thiamethoxam is also included with this application in Appendix A.
- B. Aggregate Exposure information is also included with this application in Appendix A.
- C. Cumulative Effects Due to Exposure to Substances with Common Mechanisms of Toxicity is also included with this application in Appendix A.
- D. Safety Determinations are also included with this application in Appendix A.

**IX. Coordination with other affected state/federal Agencies:**

The North Dakota Game and Fish Department, the North Dakota Department of Health and the local U.S. Fish and Wildlife Service have received copies of this request. Any comments will be forwarded

**X. Notification of Registrant**

Novartis Crop Protection is the registrant of Helix seed treatment. Novartis has been notified that the North Dakota Department of Agriculture has applied for a specific exemption for the use of Helix Herbicide on canola. Novartis has stated that it supports the use of Helix seed treatment on canola under a Section 18 specific exemption in North Dakota and it will provide the required quantity of product and technical and sales support for this use. Enclosed with this application is a letter of support from Novartis.

**XI. Description of Proposed Enforcement Program**

The North Dakota Department of Agriculture will randomly monitor seed facilities to ensure that all label restrictions are followed.

**XII. Information Required for a Specific Exemption**

Discussion of Events or Circumstances Which Brought About the Emergency Condition

28-000292  
BARCODE: D260752

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BRAN: ERB1 11/3/99 PROJ DATE: / /  
SECT: IO 11/3/99  
REVR : 11/3/99  
CONTR: 12/16/99

*Assigned to your branch since you have the other two active ingredients. Please call me if I need to reassign bean. Thanks! Steve*

*Unregistered new chem 11/3/99 evaluating Thiamethoxam, difenothiazine*

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

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260750	EAB/IO	11/02/99	11/22/99	Y	N	Y
260760		11/02/99	11/22/99	Y	N	Y



NOVARTIS

September 24, 1999

Barry Coleman  
Northern Canola Growers Association  
4007 State Street  
Bismark, ND 58501

Novartis Crop Protection, Inc.  
P.O. Box 18300  
Greensboro, NC 27419-8300  
www.cp.us.novartis.com

Tel 336 632 6000

**SUBJECT: SECTION 18 EMERGENCY EXEMPTION FOR THE USE OF  
HELIX™ ON CANOLA SEED IN NORTH DAKOTA AND IDAHO**

Dear Dr. Coleman:

This letter is to notify you of Novartis Crop Protection, Inc. support for the use of Helix, under a FIFRA Section 18 registration, to control flea beetles and certain seed borne and damping off diseases of canola. As you know, the registration petition package for Helix, including a tolerance petition for canola, is currently under joint review with the US EPA and PMRA in Canada. The residue final report submitted with the registration petition was assigned MRID # 44703528 by the EPA. Novartis does not expect federal registration in time for the 2000 use season.

We have determined that adequate stocks of Helix are available during the expected time period for the emergency exemption. Upon request, Novartis will assist in determining the sales figures for the state's reporting procedures under FIFRA Section 18.

Included with this letter of support are the following documents to ensure a successful Section 18 registration petition:

- DRAFT supplemental Section 18 label.
- EPA Notice of Filing for Helix, dated May 5, 1999 (See Page 6 of 15)

Please feel free to contact me with any further questions or concerns.

Regards,

Patrick McCain  
Regulatory Affairs Specialist II  
PH 1 800 334 9481 x7317  
FAX 336 292 6374

cc: George Robinson - ID Dept. of AG  
Jeff Olson - ND Dept. of AG

Enclosures (label + Notice of Filing)  
FN:NDIDHelixCanola99Sec18ltr-9/24/99

(Master Label)

**THIS PRODUCT IS APPROVED FOR EMERGENCY USE ONLY UNDER FIFRA SECTION 18 EXEMPTION IN NORTH DAKOTA AND IDAHO. THE USER MUST HAVE A COPY OF THE EPA NOTICE OF APPROVAL WHICH PERMITS USE OF THIS PRODUCT DURING 2000 IN THEIR POSSESSION AT THE TIME OF PESTICIDE APPLICATION AND FOLLOW ALL DIRECTIONS FOR USE, RESTRICTIONS, AND PRECAUTIONS. CONTACT YOUR STATE DEPARTMENT OF AGRICULTURE OR STATE AGENCY RESPONSIBLE FOR PESTICIDE REGULATION TO DETERMINE IF A SECTION 18 IS IN EFFECT. ALL PRODUCT WHICH IS NOT USED MUST BE RETURNED TO THE DEALER WHERE PURCHASED BY DECEMBER 31, 2000.**

HELIX™

INSECTICIDE WITH FUNGICIDE

A seed treatment product for control of certain insects and diseases of canola

For use only in commercial seed treatment plants

Active Ingredient:

Thiamethoxam (ISO proposed): 3-(2-Chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5] oxadiazinan-4ylidene-N-nitroamine.....	20.70%
Difenoconazole: (CAS No: 119446-68-3) .....	1.25%
(R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester (CAS No: 70630-17-0) .....	0.38%
Related Compounds .....	0.01%
Fludioxonil: (CAS No. 131341-86-1) .....	0.13%
Other Ingredients:	77.53%
Total:	100.00%

Helix contains the following amounts of active ingredient per gallon:  
2.23 lbs. thiamethoxam; 0.14 lbs. difenoconazole; 0.04 lbs. (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester;  
0.01 lbs. fludioxonil.

Made in Canada.

EPA Est. 71478-CAN-001

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See storage, disposal, and precautionary statements and directions for use inside booklet.

## **DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY**

**IMPORTANT:** Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product. If terms are not acceptable, return the unopened product container at once.

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### **CONDITIONS OF SALE AND WARRANTY**

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The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application all of which are beyond the control of Novartis Crop Protection, Inc. or the Seller. All such risks shall be assumed by the Buyer.

Novartis warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above. **Novartis makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Novartis or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** Novartis and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty**, which may be varied only by agreement in writing signed by a duly authorized representative of Novartis.

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**DIRECTIONS FOR USE**

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It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed-treatment applications at or immediately before planting.

**FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR INSECT AND/OR DISEASE CONTROL, AND/OR ILLEGAL RESIDUES.**

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality and seed storage conditions beyond the control of Novartis, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.

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## GENERAL INFORMATION

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Helix is a seed treatment product that contains both insecticide and fungicide components with activity against flea beetles and certain seed borne and damping off diseases of canola. Thiamethoxam, the insecticide component provides activity against flea beetles and the remaining components are fungicides with activity against damping off diseases caused by *Pythium* spp., *Fusarium* spp., *Rhizoctonia* spp. and seed-borne blackleg (*Leptosphaeria maculans*). Thiamethoxam is the active ingredient in Adage 5FS, difenoconazole, (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester, and fludioxonil are the active ingredients in Dividend®, Apron XL™ LS, and Maxim® 4FS, respectively.

**Note:** (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester is a systemic fungicide having a specific mode of action. (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester could be subject to development of insensitive strains of fungi. Development of insensitivity cannot be predicted. Therefore, Novartis cannot assume liability for crop damage resulting from insensitive strains of fungi. Consult your State Agricultural Experiment Station or Extension Service Specialist for guidance and ways to control any possible insensitive strains of fungi which may occur.

### Mixing Procedures

Helix is especially formulated as a ready to apply seed treatment. An EPA-approved coloring agent, C.I. Pigment Blue No. 15, has been added to the formulation. No additional colorant, dyes, binders, or water are needed. Apply utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of insect or disease control. Consult the manufacturer of the application equipment you plan to use for suitability for this application and for instructions on operation and calibration of the equipment. Allow seed to dry before bagging.

Federal law requires that bags containing treated seed shall be labeled with the following information: "This seed has been treated with thiamethoxam insecticide and fludioxonil, difenoconazole, and (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester fungicides." Do not use for feed, food, or oil purposes. Store away from feed and foodstuffs. Treated seed can only be shipped to states approved by EPA in Section 18 authorization letter.

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## CANOLA

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To provide early season protection against flea beetles, and damping-off diseases caused by *Pythium* spp., *Fusarium* spp., *Rhizoctonia* spp. and seed-borne blackleg (*Leptosphaeria maculans*) apply Helix at 23 fluid ounces of product per 100 lbs. of seed.

**Rotational Crops:** Treated areas may be replanted immediately following harvest or as soon as practical following the last application with wheat or canola. Barley, cole crops, cotton, cucurbit vegetables, fruiting vegetables, leafy vegetables, pome fruit, sorghum, tobacco, tuberous and corn vegetables, and may be planted 30 days after the last application of Helix. For all other crops, a 120 day plantback interval must be observed.

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## STORAGE AND DISPOSAL

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### Pesticide Storage and Disposal

Store in a cool, dry place. Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

### Container Disposal

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.



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## **PRECAUTIONARY STATEMENTS**

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### **Hazards to Humans and Domestic Animals**

#### **CAUTION**

Harmful if inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### **Statement of Practical Treatment**

**If in eyes:** Flush with plenty of water. Call a physician if irritation persists.

**If on skin:** Wash with plenty of soap and water. Get medical attention.

**If swallowed:** Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

**If inhaled:** Move to fresh air.

**Note to Physician:** There is no specific antidote if Helix is ingested. Induce emesis or lavage stomach treat symptomatically.

**Note:** Workers must wear long pants, long sleeve shirts, and chemical-resistant gloves when applying Helix as a seed treatment.

#### **Environmental Hazards**

This product is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsates.

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Helix™, Apron XL™, Maxim®, and Dividend® are trademarks of Novartis

This product is protected by U.S. Patent Nos. 4,705,800; 5,266,585; 5,723,491; 5,843,982; 5,852,012

Other patents pending.

No license is granted under any non-U.S. patent(s).

©1999 Novartis

Novartis Crop Protection, Inc.  
Seed Treatment Products  
Greensboro, North Carolina 27419

NCP

[LABELH-W/HELIX-A] - ccg - 9/28/99

261132

The following are excerpts taken from agricultural alerts from the North Central Research Center in Minot, North Dakota for the 1999 growing season:

**From Ag Alert – May 27, 1999:**

**!!FLEA BEETLE ALERT!!**

Flea beetles are rapidly emerging with the warm, sunny weather. Sticky trap catches have increased from last week. Some growers are experiencing economic levels of flea beetle damage in fields planted early (late April to early May) and with Gaucho-treated seed. Due to the cool, rainy weather, germination was delayed from the usual seven days and the seeds sat for 2 -3 weeks. The seedlings are emerging through crusted and

other difficult soil conditions. Unfortunately, gaucho has little efficacy against flea beetles after 21 days. So, field monitoring is very important especially on these early planted fields treated with gaucho or non-treated. Fields planted last week are already emerging and catching up to the earlier planted fields which quit growing during the cool, rainy period. The Economic Threshold (E.T.) for flea beetle on canola is 25% foliar damage (pitting) during the seedling stage. Remember, scout several areas of the field. If fields are above E.T., a foliar treatment of Warrior is recommended. The insecticide trial at Minot will provide interesting data on different seed and foliar treatments this year!

**From Ag Alert – June 11, 1999**

**VERY HEAVY FLEA BEETLE PRESSURES ON CANOLA!**

Flea beetles are still moving into canola fields regardless of the planting date. Many acres are being or will be treated in the early crop stages. Unfortunately, some gaucho-treated fields have also had to be sprayed. There are several possible reasons why the gaucho-treated seed isn't working as well this year. On early seeded canola fields, late April to early May, seeds did not germinate and emerge for 2-3 weeks due to the cool,

wet weather, and gaucho has little efficacy against flea beetles after 21 days. Remember, flea beetles are actively feeding for a 3-4 week window, and seedlings with low levels of pesticides may not be killing flea beetles. Another explanation is the wet, rainy weather has leached some of the insecticide preventing the seed from absorbing the insecticide during germination. In turn, the chemical degradation has reduced the efficacy or time span when the insecticide is effective. In addition, flea beetles appear to be concentrating on the reduced acreage of canola planted this year. So, flea beetle pressures are high on a relatively small number of fields. Some observations also indicate more flea beetle problems on gaucho-treated seed for the smaller seeded (150,000 seeds per pound) and less vigorous varieties of canola like Hudson. Research from Canada indicates that the larger seeded (70,000

The crucifer flea beetle, *Phyllotreta cruciferae*, and the striped flea beetle, *Phyllotreta striolata*, are significant pests of seedling canola. Yield losses of 10% are common in canola when flea beetles are abundant even when the crop is protected with insecticides. Flea beetles injure the plants by feeding on leaf tissue, stems, and pods. During seedling emergence, severe stand loss can occur if flea beetles are present in large numbers and the cotyledon leaves are the only green tissue available. The first two weeks after seedling emergence is when flea beetle injury has the greatest impact. Injury results in stand loss and growth rate reduction. This results in poor stands, uneven maturity, reduced seed yield, and contributes to seeds with elevated chlorophyll content. Over the past five years, flea beetle pressure has been increasing in the northern-tier states, resulting in significant losses to canola producers in situations where the pest was not adequately controlled. The flea beetle populations were extreme last year on canola and were even worse in 1999.

Flea beetles pose the greatest threat to canola seedlings when hot, dry weather conditions occur during emergence. Under these circumstances, flea beetles are very active and can migrate in large numbers to newly emerging canola fields. The dry conditions enhance the impact feeding injury has on the seedling, causing severe moisture stress and rapid death of the seedling.

The most effective and efficient method of managing flea beetles in canola is the use of seed treatments. Currently, Gaucho (imidacloprid) is the only active ingredient federally registered for use on canola. However, as indicated by the excerpts below and by the enclosed data from Dr. Janet Knodel, the protection offered by Gaucho was not sufficient this year to adequately control flea beetle pressures. Helix will provide another option to protect canola from flea beetles and ensure growers do not sustain significant economic losses.

Last year, Dr. Phil Glogoza, entomologist with North Dakota State University, stated that the flea beetle outlook indicated that populations were at high risk levels in the north central counties of the state. This high risk area is where 80% (680,000 acres) of the canola acreage is located. He also indicated that the populations at that time throughout the region would likely inflict serious injury to canola seedlings. His predictions were correct. He also stated if large populations of flea beetles combined with the stated weather conditions occurred, even the Gaucho treated canola seedlings could require supplemental treatment to limit feeding injury, which Dr. Knodel detailed in the enclosed memorandum.

## Discussion of Economic Loss

### *Discussion of Economic Loss*

The following tables provide information on canola production and its economic impact on the states of North Dakota and Minnesota. Data is from the past six production years and the estimated impact for 1999.

#### **Summary of Canola production in North Dakota from 1993 to 1999.**

Year	Acres Planted	Acres Harvested	Yield Per Acre	Production	Marketing Year Avg. Price	Value of Production	Value per Harvested Acre
	(000 Acres)		(Lbs.)	(000 Lbs.)	(\$/Cwt.)	(000 Dols.)	(Dols.)
1993	48.0	46.5	1,230	57,195	9.05	5,176	111.31
1994	130.0	126.0	1,400	176,400	10.50	18,522	147.00
1995	215.0	211.0	1,220	257,420	11.00	28,316	134.20
1996	220.0	217.0	1,380	299,460	12.90	38,630	178.02
1997	500.0	480.0	1,230	590,400	11.10	65,534	136.53
1998	793	780.0	1,285	1,002,300	11.00	110,253	141.35
1999	850*	---	1,320	1,122,000	9.70	108,834	128.04

\* 1999 acreage and revenue estimates based on seed sales within the region.

seeds per pound) varieties, like Hyola, can endure more flea beetle damage.

Field monitoring is very important for fields in the susceptible stage - seedling to early true leaves development. The Economic Threshold (E.T.) for flea beetle on canola is 25% foliar damage (pitting). Remember, scout several areas of the field. If fields are above E.T., a foliar treatment of Warrior (Section 18) is recommended. After plants reach the 4-6 true leaves, canola plants can sustain and outgrow most flea beetle damage. Fields in the two true leaf stage are being treated a second time in some areas with heavy flea beetle pressures (>50% defoliation).

**From Ag Alert – June 17, 1999**

#### **FLEA BEETLE PRESSURES CONTINUE ON CANOLA!**

Flea beetles continue their feeding frenzy! Some fields have been sprayed twice to suppress economic damage. Flea beetles have been observed feeding on the new tender leaves of older plants (>4 leaves) and killing the growing point! Continue scouting even in the later stages. On the brighter side, flea beetle pressure should be winding down in the next week.

**From Ag Alert – September 13, 1999**

#### **REVIEW OF FLEA BEETLE SEASON 1999--CANOLA**

The flea beetle activity started the first week of June and continued until the end of June during 1999! Note the extremely high numbers of flea beetles at Mohall with an average trap catch of 1300 beetles per trap week during peak activity. At the NCREC, populations were not as high as the Mohall area, but the activity period was similar (early June-early July). The duration of the peak activity was long about 3-4 weeks. In contrast, the 1998 populations of flea beetles started to increase earlier in the year (May 21st), and for a shorter duration (only 2 weeks) than the 1999 populations. Due to the very heavy flea beetle pressures and the prolonged duration of feeding activity, the canola crop was severely attacked by flea beetles during 1999. Many canola fields had to be rescued with one or more applications of a foliar insecticide regardless of whether the seed was treated with Gaucho or not.

**Market Price of Canola:** \$9.70 per Cwt.

**Yield Potential:** 1,320 lbs. per acre, based on industry estimates.

**Budgeted production cost:** \$127.18 per acre for Helix treated canola, and \$124.18 per acre for Gaucho treated canola. These figures are based on NDSU projected crop budgets for canola for 1999, with an insecticide cost of \$6.60 removed and a price of \$8.00/acre for Helix and \$5.00/acre for Gaucho added back in.

In the information gathered in insecticide trials this year at the North Central Research Center, Gaucho had an average pit count of 42 pits per plant, whereby the untreated check had counts of 45 pits per plant. This indicated that Gaucho was not able to provide control at levels significantly higher than an untreated check. Therefore, in the first scenario, a 65% yield loss is projected from canola treated with Gaucho. Adequate control is projected with the use of Helix, based on trial data results from this year. In the second scenario, a 25% yield loss is projected from slightly less flea beetle pressure in certain areas, and therefore, higher levels of control from Gaucho.

**Projected Losses due to Severe Flea Beetle Injury, or 65% yield reduction, in North Dakota for 1999.**

Option	Yield (Lbs.)	Price (\$/Cwt.)	Gross Revenue (\$/A)	Budgeted Cost (\$/A)	Net Rev/Loss (\$/A)
Section 18	1,320	9.70	128.04	127.18	0.86
W/Gaucho	462	9.70	44.81	124.18	-79.37

These loss projections could impact 135,000 acres of canola, or 16% of the state acreage. These acres are located in the north central counties of North Dakota. This area represents the largest canola production region for the state. Historically, this region has the largest populations of flea beetles that impact canola.

**Projected Losses due to Moderate Flea Beetle Injury, or 25% yield reduction, in North Dakota for 1999.**

Option	Yield (Lbs.)	Price (\$/Cwt.)	Gross Revenue (\$/A)	Budgeted Cost (\$/A)	Net Rev/Loss (\$/A)
Section 18	1,320	9.70	128.04	127.18	0.86
W/Gaucho	964	9.70	93.51	124.18	-30.67

Canola acreage thought to be at moderate risk is concentrated in the northeast counties of North Dakota. In these areas, flea beetle populations have been smaller. Though this area has experienced above normal precipitation patterns in the previous four growing seasons, the rainy periods have occurred in the middle of July, causing severe problems in wheat production. However, rainfall during planting and stand emergence in late May has been more erratic. If dry weather conditions prevail during planting, the flea beetles present in this area could inflict serious injury to canola seedlings.

This level of injury may also be anticipated in fields where flea beetle populations are high, conditions are dry, and the approved seed treatment was used. Under these conditions, Gaucho-treated canola has experienced feeding injury levels where yields were reduced.

**Summary.** The difference in net revenue between the Section 18 (Helix) and the next best alternative (Gaucho) is \$80.23 per acre for severely infested canola fields and \$31.53 for moderately infested canola fields. As can be seen, the returns with the treatment of Gaucho will be well outside the five year average for canola.

**Summary of Canola production in northeast Minnesota from 1993 to 1999.**

Year	Acres Planted	Acres Harvested	Yield Per Acre	Production	Marketing Year Avg. Price	Value of Production	Value per Harvested Acre
	(000 Acres)		(Lbs.)	(000 Lbs.)	(\$/Cwt.)	(000 Dols.)	(Dols.)
1993	18.2	---	1,230	22,386	9.05	2,026	111.32
1994	30.6	---	1,400	42,840	10.50	4,498	147.00
1995	60.0	---	1,220	73,200	11.00	8,052	134.20
1996	69.0	---	1,380	95,220	12.90	12,283	178.02
1997	120.0	---	1,230	147,600	11.10	16,384	136.53
1998	180.0	---	1,285	231,300	11.00	25,443	141.35
1999	78.0		1,300	101,400	9.70	9,835	126.10

\* 1999 acreage and revenue estimates based on seed sales within the region.

**Summary of Canola Revenue per Acre in North Dakota from 1993 to 1999.**

Year	Yield Per Acre	Marketing Year Avg. Price	Value per Harvested Acre	Production Cost	Net Return
	(Lbs.)	(\$/Cwt.)	(Dols.)	(\$/A)	(\$/A)
1993	1,230	9.05	111.31	101.65	9.66
1994	1,400	10.50	147.00	104.15	42.85
1995	1,220	11.00	134.20	113.44	20.76
1996	1,380	12.90	178.02	120.82	57.20
1997	1,230	11.10	136.53	124.03	12.50
1998	1,285	11.00	141.35	130.00	11.35
1999	1,320	9.70	128.04	125.78	2.26

\* 1999 revenue estimates based on projected NDSU crop budgets.

Economic loss estimates are based on previously conducted field trials to determine efficacy of soil and foliar insecticides at preventing injury to seedling canola. These observations have led to general classifications of flea beetle feeding injury and resulting yield loss. These classifications are: severe, 60 to 70 percent yield loss; and moderate, 20 to 30 percent yield loss.

***Estimated Revenues for the sites to be treated***

In the following analysis, these assumptions are made:

**Cost of Insecticide:**

Helix = \$8.00 per acre.

Gaucho= \$5.00 per acre.